K130801
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510(k) Summary

JUN 14 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number: _____

1. **Date of submission:** March 13, 2013

2. **Submitter**

SonoScape Company Limited

Address: Yizhe Building, Yuquan Road,Nanshan, Shenzhen 518051, P.R.China

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Contact Person: Toki Wu

E-mail:Faith@sonoscape.net/wusq@sonoscape.net

3. **Proposed Device Identification**

Trade/Proprietary Name: S11 Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducers

Classification:

21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Classification Panel: Radiology

Device Class: II

4. **Legally Marketed Predicate Device**

SonoScape Company Limited, Diagnostic Ultrasound System, Model S6 has been cleared by FDA through 510(k) No.K112602 (Decision Date – November 07, 2011).

5. Device Description

The SonoScape S11 Digital Color Doppler, Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 4D.

6. Intended Use Statement

The SonoScape S11 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

7. Testing

Laboratory testing was conducted to verify that the S11 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output

Measurement Standard for Diagnostic Ultrasound Equipment" and "NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

IEC 60601-1: 1988+A1:1991+A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

8. Clinical Test:

No clinical testing was required.

9. Comparison Table

The differences between the S11 and the predicate device S6 in almost every part are listed in the tables below.

Table 1 General Comparison

ID	Comparison Items	Proposed Device Sonoscape S11	Predicate Device Sonoscape S6	Remark
2	**Classification Name**	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	SE
3	**Product Code**	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	SE

ID	Comparison Items	Proposed Device Sonoscape S11	Predicate Device Sonoscape S6	Remark
4	**Regulation Number**	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	SE
5	**Panel**	Radiology	Radiology	SE
6	**Class**	II	II	SE
1	**Intended Use**	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	SE
7	**Probe Type & Connectors**	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz	SE
		C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz C354 Curved Array, 2.0-5.0 MHz	C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz	SE **Analysis 1**
		C611 Micro-curved Array, 4.0-8.0 MHz	C611 Micro-curved Array, 4.0-8.0 MHz	SE
		VC6-2 Curved Array, 2.0-6.0 MHz	VC6-2 Curved Array, 2.0-6.0 MHz	SE
		6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz	6V1 Micro-curved Array, 4.0-8.0 MHz 6V3 Micro-curved Array, 5.0-9.0 MHz EC9-5 Micro-curved Array, 5.0-9.0 MHz	SE
		2P1 Phased Array, 2.0-4.0 MHz	2P1 Phased Array, 2.0-4.0 MHz	SE

ID	Comparison Items	Proposed Device Sonoscape S11	Predicate Device Sonoscape S6	Remark
		5P1 Phased Array, 4.0-7.0 MHz	5P1 Phased Array, 4.0-7.0 MHz	
		Multi-port connector connects 3 transducers	Multi-port connector connects 2 transducers	SE Analysis 2
8	Acoustic Track	TRACK 3	TRACK 3	SE

Table 2 Functions Comparison

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
9	Design	Based on an embedded Linux operating system.	Based on an embedded Linux operating system.	SE
		Based on a 64 channel full digital beam former.	Based on a 64 channel full digital beam former.	SE
		Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	Autocorrelation for color processing and FFT for pulse and CW Doppler processing.	SE
		Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	Supporting Linear, Curve linear and Phase array probes from 2 to 15 MHz.	SE
		Cine play back capability	Cine play back capability	SE
		Image file archive	Image file archive	SE
		Software upgrades with USB flash drive.	Software upgrades with USB flash drive.	SE
		Digital Scan Converter 800×600	Digital Scan Converter 800×600	SE
10	Operation Controls	TGC 8 slider	TGC 8 slider	SE
		Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	SE
		Image sector size: 32 lines to full B (256 lines)	Image sector size: 32 lines to full B (256 lines)	SE
		Image Sector position: Steering within full maximum	Image Sector position: Steering within full maximum	SE
		B orientation flip :L/R key with marking on the screen	B orientation flip :L/R key with marking on the screen	SE
		B Dynamic range control: preset 14 curves over 140 dB	B Dynamic range control: preset 14 curves over 140 dB	SE
		Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	SE
		Focal Number: 12 focal zone setting	Focal Number: 12 focal zone setting	SE
		B persistence: 0-95%	B persistence: 0-95%	SE
		Image Processing: Smoothing,	Image Processing: Smoothing,	SE

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
		edge enhancement	edge enhancement	
		PW sweeping speed 2,4,6,8 sec over display	PW sweeping speed 2,4,6,8 sec over display	SE
		PW Wall filter setting:16 settings,25 to 750 HZ	PW Wall filter setting:16 settings,25 to 750 HZ	SE
		PW sample volume:0.5 to 20mm	PW sample volume:0.5 to 20mm	SE
		PW/B update: with UPDATE key	PW/B update: with UPDATE key	SE
		PW cursor steering: Steer soft key	PW cursor steering: Steer soft key	SE
		PW angle correction:0 to 80 degree user control	PW angle correction:0 to 80 degree user control	SE
		PW spectrum dynamic range:10 preset curve over 15-48 dB	PW spectrum dynamic range:10 preset curve over 15-48 dB	SE
		Spectrum baseline shift and invert	Spectrum baseline shift and invert	SE
		Color ROI setting: trackball and set key to control size and position	Color ROI setting: trackball and set key to control size and position	SE
		Color steering on flat probe:±20 ±160	Color steering on flat probe:±20 ±160	SE
		Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	Color Wall Filter: Color wall filter with 16 selection, 25-750 of PRF	SE
		Color priority-B priority soft menu	Color priority-B priority soft menu	SE
		Color Packet size: preset per Exam, horizontal, vertical, off	Color Packet size: preset per Exam, horizontal, vertical, off	SE
		Zoom adjustable	Zoom adjustable	SE
		Freeze control: Toggling freeze key	Freeze control: Toggling freeze key	SE
		Cine control: step, play backward, play continuously	Cine control: step, play backward, play continuously	SE
11	**Operation Mode**	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 4D Mode Color M Mode	B, M, PW, CW, CFM, DPI, TDI, Tissue Harmonic Image 3D/4D Mode Color M Mode	SE **Analysis 3**
12	**Display Modes**	Dual B, Quad Display, B and M, B and Doppler	Dual B, Quad Display, B and M, B and Doppler	SE

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
		B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging..	B + Color, Dual B(Flow) Triplex mode: B,CFM, and PW/CW ; B,DPI, and PW/CW;B,THI and Color M, steer M Dual B and Color in real time Compound Imaging, Panoramic Imaging, Trapezoid Imaging.	
13	Measurement Items	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	Distance; area; circumference; calipers; volume, velocity, HR, PI, RI. Cardiac. OB/GYN, Urology, Vascular and small part package	SE
14	Cine Loop	Automatic review/ manual review	Automatic review/ manual review	SE
		Review speed can't be adjust	Review speed can be adjust	SE

Table 3 Specifications Comparison

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
15	Power Supply	Voltage: 100-240 VAC	Voltage: 110-240 VAC	SE Analysis 4
		Frequency: 50/60 Hz	Frequency: 50/60 Hz	SE
		Power Consumption: 100-240V AC, 2.7-1.2A	Power Consumption: 110-240V AC, 2.7-1.2A	SE
16	Operating Condition	Temperature: 10~40℃	Temperature: 10~40℃	SE
		Relative humidity: 30~85%	Relative humidity: 30~85%	SE
		Air pressure: 700hPa ~1060hPa	Air pressure: 700hPa ~1060hPa	SE
17	Storage Condition	Temperature: -20~55℃	Temperature: -20~55℃	SE
		Relative humidity: 20~90%	Relative humidity: 20~90%	SE
		Air pressure: 700hPa ~1060hPa	Air pressure: 700hPa ~1060hPa	SE
18	Screen Size	15 inch Widescreen LCD monitor	15 inch Widescreen LCD monitor	SE
19	Acoustic Output	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm^2 maximum.	Track 3: MI,TIS,TIC,TIB Derated ispta: 720Mw/cm^2 maximum.	SE

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
		TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm^2 max	TIS/TIB/TIC: 6.0 Maximum, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190W/cm^2 max	

Table 4 Safety Comparison

ID	Comparison Items	Proposed Device Sonoscape S11	Predicate Device Sonoscape S6	Remark
20	**Electrical Safety**	-IEC 60601-1	-IEC 60601-1	SE
21	**EMC**	-IEC 60601-1-2	-IEC 60601-1-2	SE
22	**Performance**	-IEC 60601-2-37	-IEC 60601-2-37	SE
23	**Biocompatibility**	-ISO 10993-5, -ISO 10993-10	-ISO 10993-5, -ISO 10993-10	SE
24	**Level of Concern Of Software**	Moderate level of concern system	Moderate level of concern system	SE

SE Analysis 1

Compare to the predicate device, the proposed device is with one more probe C354. But the intended use of C354 is the same to the C344 and C362, no new intended use is added, therefore, the intended use could be considered Substantially Equivalent.

SE Analysis 2

The proposed device has 3 probe connection ports and the predicate device has 2 probe connection ports, but both of them comply with IEC 60601-1 and IEC 60601-1-2.

SE Analysis 3

Operation Mode, compare to the predicate device, the proposed device doesn't have 3D function. But both of them comply with AAMI UD2 and IEC 60601-2-37. Therefore, they are considered to be substantially equivalent, so the SE is not affected.

SE Analysis 4

The Voltage of the proposed device and the predicate device are 100-240 VAC and 110-240 VAC respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

Discussion of Substantially Equivalent

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10. Substantially Equivalent Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S11 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

SonoScape Company Limited
% Ms. Toki Wu
Regulatory Affairs Manager
Yizhe Building, Yuquan Road, Nanshan
Shenzhen, Guangdong 518051
CHINA

Re: K130801
Trade/Device Name: S11 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 13, 2013
Received: March 22, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers for use with the S11 Digital Color Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1 Phase Array	C611 Micro-curved Array	L743 Linear Array
5P1 Phase Array	C362 Curved Array	L741 Linear Array
6V1 Micro-curved Array	C344 Curved Array	L742 Linear Array
6V3 Micro-curved Array	C354 Curved Array	
EC9-5 Micro-curved Array	VC6-2 Curved Array	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Deputy Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130801

Device Name: S11 Digital Color Doppler Ultrasound System

Indications for Use:

The SonoScape S11 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Transvaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
X		

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130801

Diagnostic Ultrasound Indications for Use Form

System: SonoScape S11
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,5
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this ppendix
Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD
Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents
Note 3: TDI Note 4: 4D
Note 5: Small Organ: breast, thyroid, testes

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130801

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P1 Phase Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130801

Diagnostic Ultrasound Indications for Use Form

Transducer: 5P1 Phase Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130801

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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510(k) K130801

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 Micro-curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: EC9-5 Micro-curved Array
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C611 Micro-curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C362 Curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2
	Abdominal	P	P	P		P	P	Note1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note1	Notes 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C344 Curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: C354 Curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	N	N	N		N	N	Note 1	Notes 2
	Abdominal	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L743 Linear Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,5
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Diagnostic Ultrasound Indications for Use Form

Transducer: L742 Linear Array
Diagnostic Ultrasound Transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,5
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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